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expensive and add to the cost of the final device. In summary, integration of prior art point-of-care medical equipment has proven difficult and the resulting devices are still very complex and therefore expensive.

One concept intended to address this problem is the approach of providing modules or defeaturized medical instrumentation for connection to other instruments. For example, the concept was discussed in "Internat. Fed. Clinical Chem., Proceedings of the 17th International Symposium, Nice, France June 1998, eds. P. D'orazio, N. Fogh-Andersen and L. Larsson, Omnipress, Madison, WI USA, 1998. pp3-15. A defeaturized blood-analysis device configured as a modular subsystem of a complete blood analyzer is described in U.S. patent 6,066,243 to Diametrics. Blood analysis devices that are modular components of a patient-monitoring system are marketed by Agilent Technologies. Though these prior-art defeaturized devices have less hardware than a self-contained analyzer, they still contain many of the components of a complete analyzer. The commercial blood-analysis modules of the prior art contain at least a micro-processor unit and software for calculation of a concentration value from raw sensor signals and for control of the measurement process, quality assurance testing and thermal control. Prior-art modules also still contain complex electromechanical subsystems for driving the analyzer's fluidics. Moreover, the defeaturized devices of the above-cited prior art are intended for incorporation into the housing of a parent instrument, together again forming a completely self-contained bedside in-vitro blood analyzer. That parent instrument in turn is a special-purpose device not a general-purpose device which could be used with many modules. Thus even these attempts at defeaturization of the measurement devices of the prior art thus far have required much costly, specialized hardware at each

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measurement location. Thus, there still exists a need for a low cost bedside instrumentation alternative.

Clinical laboratory regulations require hospitals to perform intermittent verification of the integrity of their blood analyzers. Hospitals administrators have also developed quality control protocols for verification of the proper function of their blood analyzers at the point of care. It is well known in the art of quality control that quality systems should effectively expose non-conformance in those elements of the instrument that are most likely to give error during use. Traditional laboratory quality control protocols have included measurements with the analyzer of liquid samples of known concentration. In point-of-care systems and especially in systems employing unit-use diagnostic devices various components of the sensor signals (signal levels and drift rate, noise level) are used to indicate non-conforming performance of the sensor and fluidics. Also, manufacturers have provided electronic devices that have been designed for use in checking the integrity of the electronics, software and electromechanical subsystems of the analyzer. The prior art contains examples of different configurations of electronic testers that have been useful in controlling point-of-care analyzers. U.S. patent 5,124,661 for example discloses an electrical test head for connection to a blood analyzer. The electrical test head plugs into the analyzer's sensor card connector and simulates the electrical outputs of a sensor card. U.S. patent 5,781,024 describes an instrument performance verification system. This patent describes a portable analyzer for contacting to a sensor card, the analyzer containing measuring circuitry and electrical verification circuitry within the single portable housing. U.S. patent 5,829,950 also discloses an electrical integrity test circuit internal to the instrument.

Summary of the Invention

It is now an object of the present invention is to provide an improved system for point-of-care in-vitro blood measurement.

It is another object to provide a point-of-care blood measuring system that includes low cost bedside components including only a minimum of hardware.

It is still a further object to provide a point-of-care blood measuring system which requires as little electrical, electromechanical and electronic hardware as possible at each blood measurement location, yet sacrifices none of the performance attributes of a self-contained analyzer at that location.

These and other objects which will become apparent below are met by a system consisting of at least one card reader for receiving a raw sensor signal from a diagnostic card, and for connection to a single general-purpose computer through a data acquisition interface. The diagnostic card reader and the companion unit-use diagnostic cards are preferably based on modified smart-card technology. Cards and card readers are compact in size and very inexpensive to produce. Diagnostic cards are modified smart cards that incorporate a blood collection structure and low cost electrochemical sensor arrays and fluidic components, as described briefly below and in detail in co-pending patent application SN 09/871,821. Sensor arrays are produced on smart-card chip modules adapted for use as electrochemical electrodes. The diagnostic card with its chip module is preferably constructed with materials and geometries that conform to ISO standards established for electronic smart cards. In use, the diagnostic cards are intended to engage

a diagnostic card with a plastic card body 101 inserted into the connector as it would be during the use of the diagnostic card and card reader.

The specific construction of the diagnostic card is not part of the present invention and is described in greater detail in co-pending application S.N. 09/871,821. The diagnostic card as shown in FIG. 2A is preferably a device that uses components with standard geometries from electronic smart-card technology with modifications to result in a card with an electrochemical sensor array and fluidics. Any diagnostic card which can produce a raw analog sensory output representative of a species concentration in the sample can be used in the system of the invention, as long as the construction of the card and the card reader allows for transmission of the raw sensory signal produced by the card to the card reader. The preferred diagnostic card includes an electrode module 102 embedded in the card body 101. The card body is a thin plastic similar in shape and size to a smart card or a credit card. The card body contains a module cavity 120, appropriate in size to accept the electrode module, and additional other measurement and reservoir chambers, openings suitable for introduction of fluids including the sample fluid and conduits or channels for movement of fluids within the card body for the purpose of performing an intended blood analysis procedure within the device and for producing an analog sensory output. These other chambers, reservoirs and channels are collectively known in the art as fluidics. The specific configuration of the fluidic elements within the card depend on the specific type of blood analysis being performed by the card. Some cards may for example incorporate a calibrator, other card types a fluid reagent, still others incorporate no on-board calibrator or reagent. The configuration of channels connecting orifices and reservoirs to the measurement chamber, depends on the sequence

of the fluid manipulation steps within the card which also depend on the type of blood analysis. As described in copending application SN. 09/871,821, the diagnostic card has at least a measurement chamber 109 (see FIG. 2A), which is the region of the card where the measurement takes place, and at least an orifice for introduction of a sample into the card, not shown in the diagram. The electrode module 102 includes the same chip carrier as used to hold the chip in the conventional electronic smart-card applications. However, in this construction, the chip-carrier is primarily used as an electrode carrier. The chip-carrier is die-cut from a substantially planar sheet consisting of a laminated bi-layer of a metal 103 and an insulator 105 with an optional adhesive layer 104 therebetween. The electrode module 102 further includes at least two electrodes as will be described in more detail below. The electrode module 102 is sealed in the module cavity 120 by a seal 108. The insulator 105 includes electrode openings 106A and 106B which extend therethrough and define the location of the two electrodes of the module. The metal layer 103 is spatially divided into two separate metal elements 103A, 103B. Each metal element extends over a region beyond the electrode openings 106 to a location at which contact can be made to an external circuit on circuit board 113 (as will be described in more detail below) by engaging contacting elements 110 on the outer surface of the electrode module 102. At the electrode openings 106A and 106B the insulator layer 105 is respectively coated with one or more thin film over-layers or membrane layers 107A, 107B of electrochemical material which extend through the openings and into electric contact with that portion of the metal element 103A, 103B respectively surrounding the opening. That portion of the metal element and the respectively contacting membrane 107 together form an electrode. Electrochemical materials which can be used for these

mechanical switch makes or breaks an electric contact when a card is inserted into the connector. The circuit board 113 generally also contains other electronic components of the signal conditioning circuitry also shown in FIG. 1, as well as the I/O connector (not shown in FIG. 2A) for connection to a data acquisition interface.

In use, sample fluid is collected into the diagnostic card body through its sample acquisition orifice and is positioned over the electrodes of the electrode module in the measurement chamber 109. The diagnostic card is then inserted into the connector slot of the card reader. Depending on the specific test card type the order in which the sample is acquired and the card is inserted into reader may differ. The diagnostic card, with its precisely located metal elements 103A, 103B of the electrode module 102, is engaged to the connector device so that the metal elements come into electrical contact with contacting elements 110 of the connector device. An electrical signal is developed at the electrodes when sample fluid within the measurement chamber comes into contact with sensor membranes 107 over the electrode openings 106. Those skilled in the art will appreciate, for example, that an analog signal in the form of a change in electrical current, voltage or conductance could be measured at the electrodes in relation to a chemical concentration in the sample fluid. This analog signal, after amplification and multiplexing within the card reader as described below, is then evaluated by a general-purpose computer using specific software installed thereon, as will be explained later. Other operations may also be performed in the chemical analysis procedure using a diagnostic card. Operations such as calibration and addition of reagent are often performed within fluidic housings of analytical devices.

It is well known in the art of in-vitro diagnostics that certain measurements require accurate control of the measurement temperature to achieve the necessary accuracy of the chemical analysis. This is the case for blood gas measurements, enzyme activity assays, coagulation time measurements and the like. FIG.2A and FIG. 2B show how thermal control elements are incorporated into the modified smart-card connector's plastic body. Each of the thermal control elements, the heater chip 115 and the thermal sensor 118, are mounted on a copper heater block 114A with insulating film coating 114B embedded in the plastic body of the smart-card connector. They are mounted so that the heater block's top surface is parallel to the diagnostic card body and lies in contact with it upon insertion of the card into the connector. The heater block is positioned so that it contacts the diagnostic card in the measurement region. Thus, in the smart-card connector they are located between the contacting ends of the two rows of contact pins 110 as shown in FIG. 2B. The electrical connection pins 115 of heater 114 and pins 119 of thermal sensor 118 on the lower surface of the respective thermal elements traverse the plastic connector body 112 and the circuit board 113. They are solder-connected to circuitry on the circuit board as shown in FIG. 2A. The approximate relative dimensions of a chip-based thermal sensor, shown in the plan view of FIG. 2B, correspond to a specific embodiment of the device using an off-the-shelf LM35 thermal sensor chip. The heater is a ceramic chip resistor in this embodiment. Those skilled in the art will recognize that there are numerous other choices for thermal sensors such as thermistors and RTD's. Moreover, other circuit elements are available for use as heaters such as diodes and power transistors and those with appropriate physical dimensions could also be used in this embodiment.

Referring to FIG. 2A, the raw analog sensor signals collected from the diagnostic card through the connector pins 110 are buffered by operational amplifiers on circuit board 113. On the electrical schematic of FIG. 1 the same sensor signals are shown passing through the connector 7 and terminating at two quad operational amplifiers 8 and 9. These operational amplifiers can be configured as voltage followers or current to voltage converters depending on whether the raw sensor output is a voltage or a current. The buffered signals are multiplexed onto a single channel using a multiplexer 10, switched by counter 11. Multiplexed signals are then amplified by the instrumentation amplifier 12 and connected to the first analog input, AI1, of the DAQ via I/O connector 13. The smart-card connector's mechanical switch 14, the position of which indicates the presence of a diagnostic card in the smart-card connector, is connected to the digital input of the DAQ. This signal informs the computer of the beginning of a measurement. The DAQ also provides ground, power supply (5V supply), and a clock signal to synchronize the card reader's multiplexers with the DAQ.

One digital output, DO1, from the DAQ is connected to module 15 including the heater and its power circuit, switching the heater on and off. The thermal control of the measurement in the card reader of this embodiment is performed by software in the general-purpose computer and not in the card reader. This allows a much simpler construction for the card reader and reduces the unit cost to a fraction of that of conventional bedside distributed diagnostic units. The temperature of the measurement zone is acquired by module 16, the thermal sensor including amplifier circuit. The amplified raw voltage signal from the thermal sensor is multiplexed into other channels of the card reader in a second multiplexer 18 and transmitted to the second analog input,